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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/065,868

11/26/2002

Xue Mei Zhou

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7590

05/31/2006

AFFYMETRIX, INC

ATTN: CHIEF IP COUNSEL, LEGAL DEPT.

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SANTA CLARA, CA 95051

EXAMINER

MILLER, MARINA I

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/065,868

Applicant(s)

ZHOU ET AL.

Examiner

Marina Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4-9, 11-16, 19-23, 25-30, 33-35 and 84 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 4-9, 11-16, 19-23, 25-30, 33-35, and 84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/10/2006 has been entered.

Claims 1-2, 4-9, 11-16, 19-23, 25-30, 33-35, and 84 are pending. Claims 3, 10, 17-18, 24, 31-32, and 36-83 are cancelled. Claims 1-2, 4-9, 11-16, 19-23, 25-30, 33-35, and 84 presently are under examination.

Applicants' arguments have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are applied.

Priority

Applicant's claim for priority under 35 U.S.C. 119(e), 120, and 122 is acknowledged. However, the applications for which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 1-2, 4-17, 19-31, 33-35, and 84 of the instant application, as set forth in the previous office action mailed 2/11/2005.

As support for the elected claims is not found in the priority applications, priority for the elected claims is granted only to the filing date of the instant application of 11/26/2002.

Claim Rejections - 35 USC § 101

Claims 1, 4-17, 19-31, 33-35, and 84 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

Claims 1, 4-17, 19-31, 33-35, and 84 were twice rejected under 35 U.S.C. 101 in the previous office action mailed 2/10/2005 and 10/19/2005 for lack of patentable utility. Applicants argue in the response filed 4/6/2006 that the specification clearly asserts specific and substantial utility for the instant invention, for example, in paragraph [0003] (page 16 of the response).

In response, it is noted that the asserted utility (*e.g.*, detecting what genes are expressed in particular organs, tissues, species and are associated with a disease) is not commensurate with the instant claims. Claim 1, for example, recites that a user selects a number of random probe set identifiers and receives from a vendor a probe array comprising probes identified by the probe set identifiers. The instant method does not have specific utility because the specific utility is determined by a product produced by the method, *i.e.*, an array, which does not have specific utility. The probe set identifiers randomly picked by a user do not tell the user what to use the array for. For example, one can randomly pick a set of probes, order them, and use the probes as a random size control for some other array. The utility of such an array is not specific. The examiner reiterates that although the claimed invention MAY have a substantial utility, the invention does not have a specific utility. Specifically, the result of the claimed method is providing a probe array which is determined on the basis of unknown probe set identifiers. In order for the result to be used for diagnostic purposes, one skilled in the art must be aware of a correlation between the information received from the method and a disease, disorder, trait, or condition to be diagnosed. Absent any disclosure about, for example, the connection of the array

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to a particular state, disease, trait, *etc.*, the asserted utility is not specific. No such information is recited in the instant claims. Thus, for the reasons stated in the previous office action, the rejection of claims 1, 4-17, 19-31, 33-35, and 84 under 35 U.S.C. 101 is maintained for lack of patentable utility.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 4-9, 11-16, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 5 recite the limitation “providing to the first user ... probe arrays produced using the customer probe array design, and responsive to the user specification of acceptance or modification.” It is not clear what limitation is intended because it is unclear what/who is responsive to the user specification, *e.g.*, the first user, probe arrays, or the customer probe array design. It is further unclear what further limitation of the method is intended by the phrase “responsive to the user specification.” As the intended limitation is not clear, claims 1-2, 4-9, 11-16 are indefinite.

Claims 1, 5, 19, 33, and 84, as amended, recite the limitation “receiving ... from a first user ... probe set identifiers that identify a first set of probe sets ..., and a second selection from the first user to share available space on a customer probe array design.” It is not clear what “second selection” represents, *e.g.*, a second selection of probes, probe set identifiers, probe

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array design, an indication of a willingness to share available space on a customer probe array, *etc.* Further, the limitation a “selection to share available space” does not limit the method step of “receiving” and represents an intended use of the selection and/or the step of receiving. Also, the phrase “selection to share available space” does not have a linguistically correct meaning. If applicants intend the limitation to mean “indicating a willingness to share available space on a customer probe array,” they should amend the instant claims to unambiguously recite the intended limitation. Therefore, for further examination purposes, the examiner interprets claim 1 as reciting receiving from a user a first and a second selection of probe set identifiers.

Claim 20 recites “the third user selection.” There is insufficient antecedent basis for this limitation in the claim. Claim 20 depends from claim 19, which does not recite “a third” user selection. As the intended limitation is not clear, claim 20 is indefinite.

Claim Rejections - 35 USC § 103

Claims 1-2, 4-9, 11-16, 19-23, 25-30, 33-35, and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson, WO 01/80155, in view of Kincaid, US 2003/0162183.

The instant claims were previously rejected over Anderson and Kincade in the office action mailed 10/19/2005. Applicants amended the instant claims and argue that none of the references describes the limitations of receiving from a first user a first selection of probe set identifiers and a second selection to share available space on an array design, identifying a second set of probe sets from the additional user, generating a probe array design comprising the first and the second set of probes together comprising a number of probes sets that is less than to a total number of probe sets available for the custom probe array design.

In response, it is noted that Anderson does disclose receiving a first and a second selection of probe set identifiers, *i.e.*, a user inputs the genetic sequence (a first selection of a probe set identifier) and then specifies a specific mutation to be tested (a second selection of a probe set identifier) (page 7, lines 22-28) (*see also* page 7, line 29 through page 8, line 2 disclosing selecting a group of target genes and adding another target to the user selection, *i.e.*, a first and a second selection). Further, Anderson discloses generating a customer probe array, providing a representation of a customer probe array to a user via graphical user interface, where a GUI is enabled to receive a user selection specifying an acceptance, modification, or rejection of the probe array design, and providing to the user a probe array, as set forth in the previous office actions mailed 2/10/2005 and 10/19/2005.

Kincaid does disclose an array design method that allows sharing of array design parameter information between commercial array users and/or vendors [0050], as set forth in the previous office action. Kincade also discloses identifying a second set of probe set identifiers selected by the additional user and generating a probe array design comprising the first and the second set of probes together comprising a number of probes sets that is less than to a total number of probe sets available for the custom probe array design [0050] (disclosing storing selected array design parameters from commercial array clients for subsequent use, by a commercial array vendor, for preparing completed array design and/or fabricating arrays according to selected array parameters; and also disclosing databases comprising in whole or in part, proprietary databases created by a commercial array vendor for use by the vendor's array customers). Motivation to combine the teachings of Anderson and Kincade was set forward in the office action mailed 10/19/2005 and is reiterated below:

“It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify a method and the system of Anderson to share a probe design, such as taught by Kincaid, where the motivation would have been to simplify array design and to allow quick and easy sharing of array designs, as taught by Kincaid [0005].”

Thus, the examiner maintains that Anderson and Kincade make the method and the system recited in the amended claims obvious, and also maintains the rejection.

Claims 1, 5-8, 11-13, 15-16, 19-22, 25-27, 29-30, 33-35, and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takegawa, WO 02/61646, in view of Kincaid, US 2003/0162183.

The instant claims were previously rejected over Takegawa and Kincade in the office action mailed 10/19/2005. Applicants amended the instant claims and argue that none of the references describe the limitations of receiving from a first user a first selection of probe set identifiers and a second selection to share available space on an array design, identifying a second set of probe sets from the additional user, generating a probe array design comprising the first and the second set of probes together comprising a number of probes sets that is less than to a total number of probe sets available for the custom probe array design.

In response, it is noted that Takegawa does disclose receiving a first and a second selection of probe sets identifiers (claim 1 recites receiving the type and the set number of a DNA chip through a communication network). Further, Takegawa discloses generating a customer probe array, providing a representation of a customer probe array to a user via graphical user interface, where a GUI is enabled to receive a user selection specifying an

acceptance, modification, or rejection of the probe array design, and providing to the user a probe array, as set forth in the previous office actions mailed 2/10/2005 and 10/19/2005.

Kincaid does disclose an array design method that allows sharing of array design parameter information between commercial array users and/or vendors, identifying a second set of probe set identifiers selected by the additional user, and generating a probe array design comprising the first and the second set of probes together comprising a number of probes sets that is less than to a total number of probe sets available for the custom probe array design [0050], as set forth above and in the previous office action. Motivation to combine the teachings of Takegawa and Kincade was set forward in the office action mailed 10/19/2005 and is reiterated below:

“It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify a method of Takegawa to share a probe design, such as taught by Kincaid, where the motivation would have been to simplify array design and to allow quick and easy sharing of array designs, as taught by Kincaid [0005].”

Claims 2, 4, 14, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tekagawa, WO 02/61646, in view of Kincaid, US 2003/0162183, as applied to claims , 5-8, 11-13, 15-16, 19-22, 25-27, 29-30, 33-35, and 84 above, and further in view of Cantor, U.S. Patent 6,007,987.

The instant claims were previously rejected over Takegawa, Cantor, and Kincade in the office action mailed 10/19/2005. Applicants did not specifically address the rejection over the combination of references. The examiner maintains that Takegawa and Kincade make claims 1,

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5-8, 11-13, 15-16, 19-22, 25-27, 29-30, 33-35, and 84 obvious, and therefore also maintains the instant rejection.

Claims 8-9 and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tekagawa, WO 02/61646, in view of Kincaid, US 2003/0162183, as applied to claims 1, 5-8, 11-13, 15-16, 19-22, 25-27, 29-30, 33-35, and 84, and further in view of Garner, U.S. 2003/0033290.

The instant claims were previously rejected over Takegawa, Garner, and Kincade in the office action mailed 10/19/2005. Applicants did not specifically address the rejection over the combination of references. The examiner maintains that Takegawa and Kincade make claims 1, 5-8, 11-13, 15-16, 19-22, 25-27, 29-30, 33-35, and 84 obvious, and therefore also maintains the instant rejection.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Miller whose telephone number is (571)272-6101. The examiner can normally be reached on 8-5, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, Ph. D. can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marina Miller
Examiner
Art Unit 1631

MARJORIE A. MORAN
PRIMARY EXAMINER

Marjorie A. Moran
5/30/06

MM